Brief Communication Communication brève

Assessing the sharpness of hypodermic needles after repeated use

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Abstract — Four gauges (14G, 16G, 18G, 20G) of single use hypodermic needles were evaluated for sharpness by measuring the force required to puncture rehydrated bovine leather. The needles began to dull after 1 use with maximum bluntness occurring within 4 to 5 uses.

Résumé — Évaluation du tranchant des aiguilles hypodermiques après un usage répété. Quatre gabarits (14G, 16G, 18G, 20G) d'aiguilles hypodermiques à usage unique ont été évalués pour le tranchant en mesurant la force requise pour percer du cuir bovin réhydraté. Les aiguilles ont commencé à s'émousser après 1 usage et la capacité de tranchant maximale se produisait durant les 4 ou 5 premières utilisations.

(Traduit par Isabelle Vallières)

Can Vet J 2018;59:1112–1114

Single use medical devices such as hypodermic needles are routinely used in human and veterinary medicine to mitigate the spread of infectious agents among patients. Within the veterinary community there has been a number of documented cases of iatrogenic transmission of infectious diseases due to the repeated use of needles (1,2). This concern coupled with needle stick injuries, and economic losses resulting from injection site blemishes and broken needles found in meat products, have been the impetus for developing needle-free injection devices (3). This technology, however, has not been widely adopted and hence single use needles remain in common use in veterinary medicine.

Livestock producers routinely reuse the same needle on multiple animals. In fact, Canada's Verified Beef Program advises producers to change needles after 10 to 15 uses (4). A recent survey of producers in the United Kingdom found that 43% of producers changed needles when the needle broke or became blunt during vaccination procedures (5). Furthermore, a survey of food and mixed animal practitioners found that veterinarians routinely use needles more than once (6). These studies underscore the pragmatic approach that producers and veterinarians apply to using single use needles; balancing strict hygienic practices with the time and cost associated with using a new needle for each injection. Apart from the potential for iatrogenic disease, single use needles dull very quickly thus requiring more penetration force, making them more susceptible to bending and breakage (7). Breakage is of concern because broken needles may become embedded within meat products. In Canada, a survey of beef processors found that 41% received at least 1 complaint annually of broken needles found in retail meat products (8).

The International Organization of Standardization (ISO) provides standards and methods for testing single use hypodermic needles (9), as well as for the stainless steel tubing (needle stem) used in their manufacture (10). There is, however, a paucity of information related to testing of hypodermic needles for use in veterinary medicine. In 1999, Hoff and Sundberg (11) published the results of a study in which 2 lengths of 16 gauge (G) and 18G needles were tested for sharpness using pig cadavers. Using a mechanical spring scale, they assessed the force (pounds) needed to penetrate the pig cadavers at 0, 10, 20, 30, and 40 repetitions or repeat penetrations. From these results it appeared that the 16G and 18G needles became dull after 20 repeated punctures. However, the force measurements were taken after every 10th needle penetration and the method of measuring force was relatively imprecise compared with current technology.

The objective of this study was to indirectly assess the number of times a single use needle could be used before signs of dulling. Dulling was determined by measuring the amount of force required to perforate tanned hide. The greater the change in required force, the greater the degree of dulling.

The testing medium was bovine vegetable tanned side leather (Tandy Leather, Fort Worth, Texas, USA). Prior to testing, the leather was rehydrated by soaking in a warm water bath for a minimum of 30 min. Leather strips, averaging 2.8 mm in thickness, were then cut from a single hide and examined for

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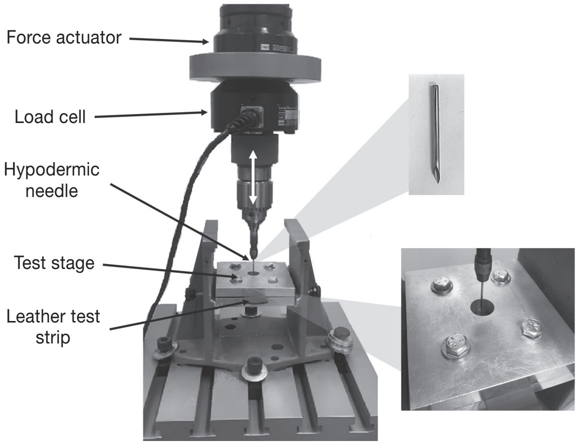

Figure 1. Each bovine leather sample was fixed to the MTS Bionix testing system by clamping the sample between 2 aluminum plates. The test needle moved axially, penetrating the leather at a perpendicular angle.

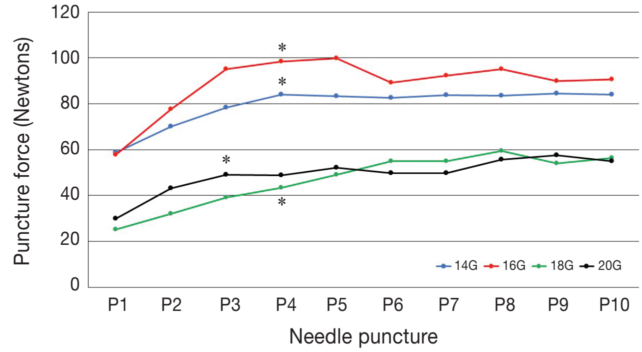

Figure 2. Mean peak penetration force (Newtons) plots for 4 single use hypodermic needles. The asterisk (*) represents the point at which the mean force required to penetrate the leather was not different ($P < 0.05$) from force required for the preceding penetration.

irregularities before testing. Single use, bevel tipped, stainless steel, hypodermic needles (Monoject; Covidien, Mansfield, Maine, USA) of 4 different gauges (G14, G16, G18, and G20) were tested. Each needle was forced to penetrate the leather 10 times, with the leather being repositioned ~10 mm between tests to ensure the needle penetrated intact leather. Testing was conducted intermittently over a 6-week period, beginning with the smallest bore needles (G20). The ten 20G needles were tested on 2 separate days (5/d). All ten 18G needles were tested the same day, while the ten 16G needles were tested over 2 consecutive days (2 and 8 needles/d). Lastly, 4 of the 14G needles were tested the same day, with the remaining 6 the following day.

A servo-hydraulic material testing system (MTS Bionix; MTS System Corporation, Eden Prairie, Minnesota, USA) controlled the axial displacement of the needles during testing, Figure 1. Two rigid aluminum plates fixed the position of the leather and ensured constant surface tension during penetration with an exposed test diameter of 9.52 mm. In preparation for testing, the needle hub was separated from the stem and the tip visually inspected for deformation. A chuck was then used to secure the needle stem in place, preventing any unwanted movement. Each needle penetrated the leather perpendicularly to the surface at a rate of 2 mm/s until puncture occurred. Peak penetration force (puncture force) was recorded at a frequency of 1000 Hz with a data acquisition system (National Instruments Corporation, Austin, Texas, USA) and converted to Newtons (N).

Descriptive statistical analysis of the mean peak penetration force for each needle gauge was completed using commercial software (STATA/SE 14.0 for Windows; StataCorp LP., College Station, Texas, USA). A mixed model with a random intercept for each needle was used to examine the differences in peak penetration force among puncture number (P_1 to P_{10}) and the gauge of the needles (14G, 16G, 18G, and 20G). An autoregressive (1) correlation structure was used to account for the order of observations within each needle. The model contained an interaction between puncture number and gauge as well as each main effect. The significance of the interaction term was assessed with a Wald test and planned *post hoc* comparisons were assessed within each gauge following each puncture and among gauges for each puncture value. Model residuals were checked graphically for normality and homogeneity of variance. Needle dulling was considered to have peaked when the force required to penetrate the leather did not change significantly from one puncture to the next. All levels of statistical significance were $P < 0.05$.

The mean force (N) required by the 14G, 16G, and 18G needles to penetrate the leather increased significantly between the 1st and 2nd puncture (P_{1-2}) and 2nd and 3rd puncture (P_{2-3}), but was not different between the 3rd and 4th puncture (P_{3-4}) (Figure 2). Specifically, the *P*-values for the 3 needles at P_{3-4} were as follows: 14G ($P = 0.08$); 16G ($P = 0.31$); 18G ($P = 0.20$). Apart from 1 exception, P_{5-6} for the 16G needles ($P = 0.001$), there were no significant changes in mean force between successive penetration points for the remainder of the study. Since there was no difference in the mean peak penetration force for the P_{3-4} interval, it can be concluded that the needle reached maximum dullness at the time of the 3rd puncture.

The 20G needles appeared to dull sooner, with no significant change in the mean force ($P = 0.07$) across the P_{2-3} interval. Hence, maximum dullness occurred at the time of the 2nd puncture.

The mean increase in total force from the 1st puncture to the puncture in which no further significant increases in force occurred were: P_{2-3} for 14G [19.5 N; 95% confidence interval (CI): 10.6 to 28.3]; P_{2-3} for 16G (37.3 N; 95% CI: 28.5 to 46.1); P_{2-3} for 18G (13.8 N; 95% CI: 5.0 to 22.7); and P_{1-2} for 20G (13.1 N; 95% CI: 6.7 to 19.5). These represented relative mean increases of 33.1% (14G), 64.7% (16G), 54.8% (18G), and 43.6% (20G) above the force required for the initial puncture.

In addition to differences in mean force between consecutive penetration time-points, the difference in mean forces across the 4 needle gauges at each penetration point were examined. A repeating pattern emerged from this analysis. At each of the 10 puncture points, there were no differences between the mean forces for the 14G and 16G needles ($P \geq 0.13$), and the mean forces for the 18G and 20G needles ($P \geq 0.32$). The mean puncture forces for all other paired comparisons, at each puncture point, were significantly different ($P \leq 0.03$). These relationships are evident in Figure 2, with the lines representing the 14G and 16G needles being very close together, as are the lines for the 18G and 20G needles.

All 4 needle gauges displayed the same general trend throughout the study, with the mean peak penetration forces being lowest at P_1 and then steadily increasing at the 2nd and 3rd puncturing events until the penetration force approached to plateau (Figure 2). This plateau can be attributed to the cessation of dulling in which the needle reached maximum bluntness. In the dulled state, the same amount of force was required for each subsequent penetration. Conceivably, had the study been extended, there may have been additional wear and dulling of the needles. Furthermore, to facilitate testing, the needle stem had been detached from the hub. Had the needle remained intact, fatigue at the stem-hub junction may have resulted in needle breakage. It has been reported (11) that lateral forces placed on the needle result in sheering at the stem-hub joint.

Although there was a linear increase in the bore size of the needles, this was not reflected in the amount of force required to penetrate the leather. Presumably, the small bore 20G needle would have required the least amount of force, with the 14G needle requiring the most. However, at P_1 the 14G and 16G required similar amounts of force, as did the 18G and 20G. Despite every effort being made to standardize the testing, the similarity in force measurements of the 14G and 16G needles and the 18G and 20G needles (Figure 2) suggests that some bias may have occurred during testing. Perhaps there were differences in the relative moisture content of the leather or the leather was not homogenous. This may also explain why the 20G line crossed that of the 18G needle in Figure 2, and why it appeared to dull sooner than the other 3 needles.

While the data are not shown, preliminary testing was also performed on 3 reusable 16G stainless steel needles (Jorvet; Jorgensen Labs, Loveland, Colorado, USA). These needles were inserted into the leather 15 times and appeared to maintain sharpness over the course of the trial; however, an insufficient number of needles were tested for statistical analysis. These findings are salient because the Verified Beef Program suggests changing needles after 10 to 15 uses (4), or when they become bent, broken, or contaminated. Presumably, this recommendation is based on the needles' degree of sharpness and an increased risk of bending and breakage. However, the recommendations do not specifically identify whether the needles are single use or multi-use needles. If the latter, then the preliminary data indicate that these needles should remain sharp for at least 15 injections.

Future studies should consider using cadavers to more closely recreate the tissue layers in which a needle is inserted. Furthermore, intact needles should be tested for sheering. This could be accomplished by inserting the needle into a cadaver to the level of the hub and then applying lateral forces, which would approximate what occurs when an animal suddenly moves while the needle is fully inserted into the tissue. Such a study could provide a science-based recommendation related to the increasing risk of needle fatigue at the stem-hub juncture with increased repeat usage. This study could be conducted on both single use and multi-use needles and with needles from different manufacturers.

The results indicate that single use needles dull rapidly, beginning after a single use. There were no significant differences in mean peak force between P_3 and P_4, and all sequential puncture points (P_5 to P_{10}) for the 14G, 16G, and 18G needles. However, mean peak forces tended to drift higher towards the end of the test. This suggests that the needles may have continued to fatigue, making them slightly less sharp and thus requiring greater force to penetrate the leather. For all intents and purposes, single use needles, regardless of gauge, become dull within 2 to 3 uses, and should be considered blunt by the 4th to 5th use. Finally, the results should not be construed as encouraging the repeated use of single use needles. Rather we draw attention to how rapidly these needles become dull, which increases the risk of bending and breaking.

Acknowledgments

We thank Dr. Sarah Parker for her help interpreting the statistical outcomes and Drs. Lope Tabil and Majid Soleimani for lending laboratory testing equipment. CVJ

References

1. Brightling P, Radostits OM. Bovine leukosis virus infection in a dairy herd in Saskatchewan. Can Vet J 1983;24:362–363.
2. Reinbold JB, Coetzee JF, Hollis LC, et al. Comparison of iatrogenic transmission of *Anaplasma marginale* in Holstein steers via needle and needle-free injection techniques. Am J Vet Res 2010;71:1178–1188.
3. Rey MR, Undi M, Rodriguez-Lecompte JC, et al. A study of the effectiveness of needle-free injection device compared with a needle and syringe used to vaccinate calves against bovine viral diarrhea and infectious bovine rhinotracheitis viruses. Vet J 2013;198:235–238.
4. Verified Beef Production Plus, Producer Resources, Injection techniques for beef cattle. Available from: http://verifiedbeefproductionplus.ca/files/producer-resources/injection_site_technique_poster.pdf Last accessed June 18, 2018.
5. Anderson DE, Silviera F. Survey of large animal veterinarians' biosecurity practices. Proc 41st American Association of Bovine Practitioners Conference, Charlotte, North Carolina, 2008:244.
6. Thacker JG, Rodeheaver GT, Towler MA, Edlich RF. Surgical needle sharpness. Am J Surg 1989;157:334–339.
7. Cresswell E, Remnant J, Butterworth A, Wapenaar W. Injection-site lesion prevalence and potential risk factors in UK beef cattle. Vet Rec 2017;180:70.
8. Van Donkersgoed J. Canadian Cattlemen Quality Starts Here — Broken needles in beef. Available from: https://www.google.ca/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact8&ved=0ahUKEwjGpLyH3IfYAhVXGMKHWO3B80QFggnMAA&url=http%3A%2F%2Fwww.agromedia.ca%2FAFMG%2FSection%25205%2520Quality%2520Assurance%2F5J2%2520Broken%2520Needles%2520in%2520Beef.pdf&usg=AOvVaw1JJQ0h8FS5LjX3sQsxTgpn Last accessed June 18, 2018.
9. International Organization of Standardization: Sterile hypodermic needles for single use — Requirements and test methods. 4th ed. Reference number ISO 7864:2016.
10. International Organization of Standardization: Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods. 2nd ed. Reference number ISO 9626:2016.
11. Hoff SJ, Sundberg P. Breakage and deformation characteristics of hypodermic devices under static and dynamic loading. Am J Vet Res 1999;60:292–298.